[ORAL ARGUMENT NOT YET SCHEDULED]

No. 24-1365

IN THE UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

DOCTORS FOR DRUG POLICY REFORM, et al.,

Petitioners,

v.

DRUG ENFORCEMENT ADMINISTRATION, et al.,

Respondents.

On Petition for Review from Orders of the
Drug Enforcement Administration

ANSWERING BRIEF FOR RESPONDENTS

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CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

Under D.C. Circuit Rule 28(a)(1), I certify the following:

A. Parties and Amici

All parties appearing in the agency proceeding and in this court are listed in Petitioners' Brief. There have been no amici or intervenors.

B. Rulings Under Review

On October 28, 2024, the Administrator of the Drug Enforcement Administration identified several individuals and entities as participants in a formal rulemaking to determine whether marijuana should be transferred from schedule I to schedule III under the Controlled Substances Act. App. 7-9. On November 21, 2024, the administrative law judge assigned to the rescheduling hearing denied petitioners' motion to intervene in the hearing. App. 390-92. Petitioners seek review of those decisions.

C. Related Cases

This case has not previously been before this Court or any other court. The petition for review in *Veterans Action Council v. DEA*, No. 24-1374 (D.C. Cir. filed Dec. 5, 2024) similarly challenges the agency's decision to not select that petitioner to participate in the same underlying formal rulemaking.

/s/ Daniel Aguilar
Daniel Aguilar

TABLE OF CONTENTS **Page**

TABLE OF AUTHORITIES

Cases: **Page(s)**

Statutes:

Rules and Regulations:

Comments on the Proposed Rulemaking from Regulations.gov:

Other:

GLOSSARY

Administrator	Administrator of the Drug Enforcement Administration
ALJ	Administrative law judge
APA	Administrative Procedure Act
App.	Petitioners' Appendix
Br.	Petitioners' Opening Brief
DEA	Drug Enforcement Administration
HHS	Department of Health and Human Services

STATEMENT OF JURISDICTION

This Court lacks jurisdiction, as explained *infra* pp. 16-28. The Department of Justice is currently conducting a formal rulemaking to determine whether marijuana should be rescheduled under the Controlled Substances Act. Petitioners seek this Court's direct review of interim orders issued by the Department's sub-agency—the Drug Enforcement Administration (DEA)—during that proceeding. But as part of the Controlled Substances Act, Congress limited this Court's jurisdiction to review of "final determinations" made by the Attorney General or her delegee. 21 U.S.C. § 877; *accord John Doe, Inc. v. DEA*, 484 F.3d 561, 567 (D.C. Cir. 2007) ("[H]ere, finality is a statutory jurisdictional prerequisite.").

Petitioners challenge DEA orders that identify which persons and entities may present live testimony, argument, and cross-examination as part of the formal rulemaking. Those interim orders—which do not determine any substantive matter about whether marijuana should be rescheduled—do not determine rights or obligations or impose legal consequences in a way that would qualify as final agency action under the Administrative Procedure Act (APA) or as a final decision under 21 U.S.C. § 877. *See John Doe*, 484 F.3d at 566 & n.4 (explaining that "the cases

applying the finality aspect of the APA guide us in construing finality" under § 877).

INTRODUCTION AND STATEMENT OF THE ISSUES

Last year, the Attorney General issued a notice of proposed rulemaking that contemplates transferring marijuana from schedule I under the Controlled Substances Act to schedule III. 89 Fed. Reg. 44597, 44597 (May 21, 2024). The Department of Justice received 43,564 comments in response to that proposal. Regulations.gov, *Schedules of Controlled Substances: Rescheduling of Marijuana*, https://perma.cc/6JEE-TNYJ.

Consistent with the Controlled Substances Act's requirement for rulemaking "on the record after opportunity for a hearing," 21 U.S.C. § 811(a), DEA has scheduled a hearing that complies with the procedures for formal rulemaking and formal adjudication under 5 U.S.C. §§ 556-557. *See* 89 Fed. Reg. 70148, 70149 (Aug, 29, 2024). More than 160 individuals and entities asked to participate in that hearing. Due to concerns about administrability, relevance, and the scope of the hearing, the DEA Administrator selected 25 individuals and entities to participate in the live hearing by presenting opening arguments, soliciting testimony from witnesses, submitting evidence, participating in cross-examination, and

presenting closing arguments. App. 7-9, 395-98. Due to the extensive nature of this evidentiary hearing, the agency currently expects that it will last at least seven weeks. App. 399-400.

Petitioners are an individual and entity who were not selected to present live evidence at the hearing, but who have already submitted written comments in response to the proposed rescheduling, and DEA will consider those comments as part of the rulemaking. 89 Fed. Reg. at 44598.

The issues presented are:

I. Whether this Court has jurisdiction under 21 U.S.C. § 877 to review DEA's decision to limit petitioners' participation in the rulemaking to their written comments.

II. Whether DEA acted contrary to the APA in selecting participants for the rulemaking's live hearing that did not include petitioners.

III. Whether the DEA Administrator has authority to regulate the conduct of the rulemaking.

STATEMENT OF THE CASE

I. Statutory and Regulatory Background

A. Congress established a comprehensive regulatory regime for marijuana and other drugs when it enacted the Controlled Substances Act in 1970. Pub. L. No. 91-513, title II, 84 Stat. 1236, 1242 (1970) (codified at

21 U.S.C. § 801 *et seq*.). The Act "consolidate[d] various drug laws on the books into a comprehensive statute" that would establish regulation for "legitimate sources of drugs" and "prevent diversion into illegal channels." *Gonzales v. Raich*, 545 U.S. 1, 10 (2005). To that end, Congress "devised a closed regulatory system making it unlawful to manufacture, distribute, dispense, or possess any controlled substance except in a manner authorized by" the Controlled Substances Act. *Id.* at 13 (citing 21 U.S.C. §§ 841(a)(1), 844(a)).

The Act divides controlled substances into five schedules "based on their accepted medical uses, the potential for abuse, and their psychological and physical effects on the body." *Raich*, 545 U.S. at 13-14 (citing 21 U.S.C. §§ 811, 812). Schedule I substances are defined as having "no currently accepted medical use in treatment in the United States" and a high risk for abuse, while schedule II-V substances have currently accepted medical uses and decreasing risks of abuse and dependence. 21 U.S.C. § 812(a)-(b).

Congress placed marijuana within schedule I. 21 U.S.C. § 812(c) sched. I (c)(10). But Congress did not expect the schedules to stay forever static, and granted the Attorney General authority to add, remove, or reschedule substances as appropriate based on new scientific and medical evidence. *Id.* § 811(a)-(b). Such rescheduling can be initiated on a petition

from an interested party, at the request of the Secretary of Health and Human Services (HHS), or on the Attorney General's own motion. *Id.* § 811(a). In making a rescheduling determination, Congress directed the Attorney General to consider several statutory factors, such as the drug's potential for abuse, the current scientific knowledge about the drug, risks to the public health, and the drug's psychic or physiological dependence liability. *Id.* § 811(c). Congress also instructed the Attorney General to comply with the United States' obligations to regulate controlled substances as required by "international treaties" then in effect, including the Single Convention on Narcotic Drugs, 1961, *approved* May 15, 1967, 18 U.S.T. 1407. *See* 21 U.S.C. § 811(d); *id.* § 801(7) (citing the Single Convention).

B. Soon after the Controlled Substances Act was passed, a private organization petitioned the Attorney General to remove marijuana from the Act's schedules or to move marijuana to schedule V. *National Organization for the Reform of Marijuana Laws (NORML) v. DEA*, 559 F.2d 735, 741 (D.C. Cir. 1977). The Department declined to reschedule marijuana and, on review, this Court remanded for further proceedings but concluded that marijuana was likely subject to a "minimum control regime of [] Schedule II" consistent with "the limits authorized by" the Single Convention. *Id.* at 757. The Department ultimately initiated a formal

rulemaking in late 1986, where "[s]even organizations or individuals participated." 54 Fed. Reg. 53767, 53773 (Dec. 29, 1989). The formal rulemaking included multiple prehearing conferences, evidence submitted from all parties, 14 days of live hearings in three different cities, proposed findings from all parties, responses by the government, and rebuttals by the parties. *Id.* The administrative law judge (ALJ) who presided over the hearing then issued a recommended decision, which the Administrator reviewed. *Id.* The entire process, from first notification of the hearing to final decision of the Administrator (keeping marijuana in schedule I), took three and a half years. *Id.* at 53773, 53784-85.

The parties to that rulemaking sought judicial review and this Court remanded for further proceedings. *Alliance for Cannabis Therapeutics v. DEA*, 930 F.2d 936, 937 (D.C. Cir. 1991). After additional explanation by the Administrator, this Court held that DEA acted reasonably in declining to reschedule marijuana, *Alliance for Cannabis Therapeutics v. DEA*, 15 F.3d 1131, 1132-33 (D.C. Cir. 1994). The Court has rejected additional efforts to compel the rescheduling of marijuana since then. *See, e.g.*, *Krumm v. DEA*, 739 F. App'x 655 (D.C. Cir. 2018) (per curiam); *Americans for Safe Access v. DEA*, 706 F.3d 438 (D.C. Cir. 2013).

II. Current Proceedings to Reschedule Marijuana

A. Scientific and medical research into marijuana has continued in the intervening decades. *See Craker v. DEA*, 44 F.4th 48, 52, 55 (1st Cir. 2022) (discussing DEA's regulatory approval of researchers who seek to "lawfully manufacture and cultivate cannabis for research purposes"). So too has public discourse about the proper regulation of marijuana. In 2022, the President directed the Attorney General and the HHS Secretary to review "how marijuana is scheduled under federal law." The White House, *Statement from President Biden on Marijuana Reform* (Oct. 6, 2022), https://perma.cc/CQF7-V6GZ. The agencies did so, and HHS issued a recommendation that marijuana be moved to schedule III. 89 Fed. Reg. at 44599.

In response, the Attorney General "sought the legal advice of the Office of Legal Counsel," 89 Fed. Reg. at 44599, including whether marijuana's placement in schedule III would satisfy the United States' obligations under the Single Convention, *Questions Related to the Potential Rescheduling of Marijuana*, 48 Op. O.L.C., slip op. at 1, 4 (2024), https://perma.cc/6DLD-75W9 (OLC Opinion). The Office of Legal Counsel concluded that the question was "a close one," *id.* at 28, but that marijuana could be placed in schedule III with additional regulations, *id.* at

33. The Office of Legal Counsel did not address whether marijuana could be placed in schedule IV or V.

After receiving that opinion, the Attorney General issued a notice of proposed formal rulemaking to transfer marijuana from Schedule I to Schedule III. 89 Fed. Reg. at 44597. The threshold issue in the rulemaking will be whether marijuana has a "currently accepted medical use in treatment in the United States" because all controlled substances without a currently accepted medical use must be placed in schedule I, while controlled substances with medical uses may be placed on less restrictive schedules. 21 U.S.C. § 812(b)(1)-(5). Whether marijuana has a currently accepted medical use has consistently been the primary focus of all previous rescheduling decisions, *e.g.*, *Alliance for Cannabis Therapeutics*, 930 F.2d at 938; *Americans for Safe Access*, 706 F.3d at 439-41, and the Department of Justice has recently taken a broader view of what may constitute currently accepted medical use, OLC Opinion 16-20.

The public submitted 43,564 comments in response to the Attorney General's proposal. Regulations.gov, *Schedules of Controlled Substances: Rescheduling of Marijuana*, https://perma.cc/6JEE-TNYJ. And the Attorney General explained that these comments "will be offered as evidence at the hearing" under 21 C.F.R. § 1308.43(g), and considered by

the Department if "competent, relevant, material, and not unduly repetitive," 89 Fed. Reg. at 44598.

The Administrator later issued a notice that the rescheduling hearing would begin December 2, 2024, 89 Fed. Reg. 70148, 70148-49 (Aug. 29, 2024). More than 160 individuals and entities asked to participate in that hearing. Declaration of Heather Achbach, Acting Section Chief of DEA's Diversion Control Division, Regulatory Drafting and Policy Support Section ¶¶ 2-3 (Achbach Declaration).[1] The Administrator considered those scores of requests and identified 25 persons and entities (in addition to the federal government) who may give live testimony, present argument, and conduct cross-examination as part of the hearing. App. 7-9, 395-401.

In an initial hearing on December 2, 2024, the ALJ assigned to the rescheduling proceeding conferred with the government and the designated participants. App. 394. All the participants intend to present witnesses and documents. App. 395-96. The evidentiary portion of the hearing is expected to last approximately seven weeks. App. 399-400.[2]

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[1] The declaration is attached to DEA's opposition to petitioners' motion for an injunction pending appeal. Opposition to Emergency Motion for an Injunction Pending Appeal add. 1-2 (D.C. Cir. Dec. 20, 2024).

[2] Due to voluntary withdrawals of certain participants, App. 343 nn.1-3, the hearing is currently scheduled for 20 parties in addition to the federal government, App. 399-400.

B. Petitioners are an organization, Doctors for Drug Policy Reform, and its president, Dr. Bryon Adinoff. Petitioners submitted a comment in response to the notice of proposed rulemaking, which the Department considered along with the thousands of other submitted comments. Regulations.gov, *Comment of Doctors for Drug Policy Reform*, https://perma.cc/TRN6-TMXW.

Petitioners also requested to participate in the formal hearing. App. 327. Petitioners stated that they believed marijuana has a currently accepted medical use and would "present additional evidence to support that assessment," App. 327, but petitioners did not identify any evidence they intended to present, *see* App. 327-32. Instead, petitioners focused on a different issue—whether marijuana's potential for abuse and dependence was lower than that of other schedule III drugs and therefore warranted placement in schedules IV or V. App. 330-32.

DEA denied petitioners' request to participate in the hearing. App. 10. DEA explained that petitioners had not "sufficiently state[d] with particularity the relevant evidence on a material issue of fact that [they] intended to present during the hearing." App. 10. DEA further noted that petitioners had not sufficiently explained how they might be "adversely affected or aggrieved," 21 C.F.R. § 1300.01(b), by the proposed

rescheduling of marijuana to schedule III to qualify as an "interested person" under the relevant statute and regulations. App. 10 (citing 21 C.F.R. § 1300.01(b)).

Petitioners then asked the ALJ overseeing the rescheduling proceeding for permission to intervene. App. 390-91. The ALJ denied that request, explaining that DEA "is endowed with the right to place reasonable limits on the number of participants in a given APA hearing." App. 391. The ALJ recognized that "thousands upon thousands of individuals and entities across the country could add value to the issues to be decided here, but they cannot all be included." App. 391.

Petitioners then asked the ALJ for an "indefinite stay of [rescheduling] proceedings," App. 1, while they sought review in this Court of DEA's decision to select some—but not all—of the 163 requesting parties to participate in the formal hearing, Achbach Declaration ¶ 3. The ALJ denied that request, explaining that "it would be illogical to expect any agency" to admit every possible participant to formal rulemakings, as "[p]roceedings would theoretically never reach a resolution." App. 2-3. As a practical matter, "they cannot all be included, and someone (in this case the Agency) must make that determination." App. 3.

C. Petitioners then filed this direct review action and asked this Court to enjoin DEA's rescheduling hearing pending appeal. Petitioners' Emergency Motion for Stay of Formal Rulemaking (D.C. Cir. Dec. 10, 2024). The Court denied that request, explaining that petitioners failed to "demonstrate a substantial likelihood of success on the merits because they have not shown that the challenged decisions of the agency are final decisions that this court has jurisdiction to review." Order at 1 (D.C. Cir. Jan. 10, 2025) (first citing 21 U.S.C. § 877; and then citing *John Doe, Inc. v. DEA*, 484 F.3d 561, 565 (D.C. Cir. 2007)). The Court explained the lack of finality was underscored by petitioners' submission of "a comment on the notice of proposed rulemaking which the government represents will be before the Administrator for decision in promulgating any final rule." Order at 1 (quotation marks omitted).

Petitioners later moved to supplement the administrative record, and the Court directed the parties to address that issue in their merits briefs. Order at 1 (D.C. Cir. Feb. 7, 2025). In their merits brief, petitioners no longer ask the Court to supplement the record or provide any argument for doing so, and so the Court need not consider the issue.

D. In addition to petitioners, more than a dozen individuals and entities have all sought to intervene in the evidentiary hearing for the

formal rulemaking. *See* DEA, *Administrative Law Judge Orders*, https://www.dea.gov/administrative-law-judge-orders (last visited March 18, 2025). Like petitioners, David Heldreth and Panacea Plant Sciences also sought a stay of the hearing based on their non-selection to participate in the formal hearing, which the ALJ denied. *See id.* Heldreth responded by suing in district court to seek review of that decision. Order at 1, *Heldreth v. Garland*, No. 2:24-cv-1817 (W.D. Wash. Nov. 27, 2024). Another entity, Veterans Action Council, similarly filed a petition for review with this Court, seeking an order to "allow our group to participate in the hearings." Petition at 1, *Veterans Action Council v. DEA*, No. 24-1374 (D.C. Cir. Dec. 5, 2024).

While those judicial actions have been ongoing, participants to the rulemaking hearing have sought various rulings from the ALJ. One of those motions, alleging *ex parte* communications, was denied by the ALJ and certified for interlocutory appeal to the Administrator. App. 404-08. While that interlocutory administrative appeal is pending, the rulemaking hearing has been stayed. App. 408.

SUMMARY OF ARGUMENT

I. The petition should be dismissed for lack of jurisdiction. This Court has jurisdiction over "final determinations" made by the DEA Administrator. 21 U.S.C. § 877; *John Doe, Inc. v. DEA*, 484 F.3d 561, 565 (D.C. Cir. 2007). Here, the Administrator has not issued any final rule on whether marijuana should be rescheduled—those proceedings remain ongoing and are not final. Petitioners seek to challenge instead an interlocutory decision determining which individuals and entities out of hundreds should present testimony, argument, and cross-examination in the live rulemaking hearing. That is the "very beginning of the adjudicatory process" and does "not constitute final agency action that is subject to judicial review." *Natural Resources Defense Council, Inc. v. U.S. Nuclear Regulatory Commission*, 680 F.2d 810, 816-17 (D.C. Cir. 1982).

II. If the Court were to reach the merits, it can properly dispose of petitioners' challenge to the agency's reasonable limits of who may participate in what could easily turn into a sprawling and unwieldy hearing. "No principle of administrative law is more firmly established than that of agency control of its own calendar." *City of San Antonio v. Civil Aeronautics Board*, 374 F.2d 326, 329 (D.C. Cir. 1967). When faced with over 160 requests from individuals and entities to participate in the live

hearing, the agency reasonably chose to select a subset of those (25 in total) who would present arguments and evidence for and against rescheduling. That decision is supported by *City of San Antonio*'s common-sense conclusion that agencies "should be accorded broad discretion in establishing and applying rules for public participation" in a formal rulemaking. *Id.* at 332 (ellipses omitted). Petitioners' attempts to depart from that conclusion or argue that DEA acted unlawfully in selecting participants are without merit.

III. Petitioners contend that the Administrator lacks authority to select who may participate in the rulemaking hearing. They cite no authority that supports that categorical proposition, which is contrary to the well-understood rule that agencies may regulate the conduct of their own proceedings.

STANDARD OF REVIEW

This Court reviews jurisdictional issues de novo. *Seed v. EPA*, 100 F.4th 257, 260 (D.C. Cir. 2024). The Court reviews agency action to determine whether it is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A).

ARGUMENT

I. The Court Lacks Jurisdiction Over The Petition

A. This Court's Jurisdiction Is Limited to Final Determinations, and DEA's Interlocutory Decision Managing an Ongoing Agency Proceeding Is Not a Final Determination

Congress granted the courts of appeals jurisdiction over petitions for direct review from "[a]ll final determinations, findings, and conclusions of the Attorney General" under the Controlled Substances Act. 21 U.S.C. § 877. The Attorney General has generally delegated enforcement of the Controlled Substances Act to the DEA Administrator, 28 C.F.R. § 0.100, and this Court has jurisdiction to review petitions from the Administrator's final decisions, *see, e.g.*, *Americans for Safe Access v. DEA*, 706 F.3d 438, 439-40 (D.C. Cir. 2013).

As this Court has explained, its jurisdiction under 21 U.S.C. § 877 is limited to "final determinations" made by DEA. *John Doe, Inc. v. DEA*, 484 F.3d 561, 565 (D.C. Cir. 2007). Whether a decision qualifies as a "final determination" for jurisdiction follows the same framework as whether a decision qualifies as "final agency action" under the APA. *Id.* at 565-66; *see id.* at 566 n.4 (explaining that "cases applying the finality aspect of the APA guide us in construing finality under 21 U.S.C. § 877"). In other words, the challenged decision must "mark the consummation of the agency's

decisionmaking process" and "must be" a decision "by which rights or obligations have been determined, or from which legal consequences will flow." *Id.* at 566 (citing *Bennett v. Spear*, 520 U.S. 154, 177-78 (1997)).

Consistent with that understanding, the Court can exercise jurisdiction over a petition concerning DEA's denial of an application to import controlled substances—that decision was "definitive," clearly determined the right to import the substances, and "establish[ed] 'legal consequences' by prohibiting importation." *John Doe*, 484 F.3d at 566-57. Likewise, the Court can exercise jurisdiction over a challenge to a DEA final rule, *Craker v. DEA*, 44 F.4th 48, 52 (1st Cir. 2022), a denial of rulemaking, *Americans for Safe Access*, 706 F.3d at 441-42, or an adjudication, *Chein v. DEA*, 533 F.3d 828, 834 (D.C. Cir. 2008).

But the Court lacks jurisdiction over challenges to DEA actions that do not qualify as final agency action. *See, e.g.*, *Advanced Integrative Medical Science Institute, PLLC v. Garland*, 24 F.4th 1249, 1260-62 (9th Cir. 2022) (dismissing challenge to a DEA guidance letter than "does not meet *Bennett*'s first" or "second condition[s]"). And 21 U.S.C. § 877 does not extend jurisdiction to allow petitions from interlocutory orders made within an ongoing DEA formal adjudication or rulemaking. Accordingly, the Sixth Circuit dismissed a petition that challenged the Administrator's

decision to quash a subpoena issued as part of an ongoing DEA administrative proceeding. *Miami-Luken, Inc. v. DEA*, 900 F.3d 738, 739 (6th Cir. 2018). The Sixth Circuit explained that 21 U.S.C. § 877 does "not permit" a court to exercise jurisdiction over the Administrator's order "while the administrative proceeding to determine [the petitioner's] registration status remains ongoing." *Id.* at 742. "Interlocutory decisions are just that—interlocutory. They are not rendered final merely because the decision is made by an agency's highest authority." *Id.* at 743.

Here, DEA's rescheduling proceeding is a formal rulemaking "made on the record after opportunity for a hearing," 21 U.S.C. § 811(a), and thus is governed by the APA's procedures for formal adjudications contained at 5 U.S.C. §§ 556-557. In that context, "a final order is [normally] one that disposes of all issues as to all parties." *Blue Ridge Environmental Defense League v. Nuclear Regulatory Commission*, 668 F.3d 747, 753 (D.C. Cir. 2012). Petitioners do not challenge such a final order—indeed, the ALJ in the proceeding has not even yet issued a recommended decision on whether marijuana should be rescheduled.

Instead, petitioners challenge DEA's direction that certain individuals and entities, but not others, should participate in a formal hearing to promulgate an eventual rule. But "[i]t is firmly established that agency

action is not final merely because it has the effect of requiring a party to participate in an agency proceeding." *Arch Coal, Inc. v. Acosta*, 888 F.3d 493, 503 (D.C. Cir. 2018) (collecting cases). That is why the mere initiation of an administrative proceeding has been well understood to have "no legal force comparable to that" of anything resembling final agency action. *FTC v. Standard Oil Co.*, 449 U.S. 232, 240-42 (1980). And petitioners cite no authority that a comparable decision to exclude some parties from participating at a live hearing—who are still able to make written submissions—is so qualitatively different as to constitute final agency action. Indeed, this Court has explained that an agency's decision to "determine the scope of its own proceedings and arrange its business accordingly" does "not impose, deny, or fix any legal right." *Puget Sound Traffic Association v. Civil Aeronautics Board*, 536 F.2d 437, 439 (D.C. Cir. 1976) (quotation marks omitted). That is why the Court regularly requires petitioners to seek judicial review from the "final decision at the conclusion of the adjudication," because broad exceptions "would wreak havoc with the final order rule." *Arch Coal*, 888 F.3d at 503.

This Court has thus repeatedly held that interim orders issued during administrative proceedings are not final when they do not independently determine rights and obligations separate from those proceedings. For

instance, a petitioner in a licensing proceeding sought to challenge an interim decision made to waive certain regulatory restrictions on a competing license application. *North American Catholic Educational Programming Foundation, Inc. v. FCC*, 437 F.3d 1206, 1207-08 (D.C. Cir. 2006). The petitioner urged that the agency's interim decision qualified as a "*final* orde[r]" that the Court could properly review. *Id.* at 1209. This Court rejected that argument, holding that the challenged decision was "incident to [the] larger licensing proceeding" and did "not mark the consummation of the agency's decisionmaking process." *Id.* (quotation marks omitted). Because the relevant jurisdictional statute permitted judicial review only for final orders, "[t]he absence of finality is sufficient to preclude our jurisdiction." *Id.*

The same reasoning was applied in *Natural Resources Defense Council, Inc. v. U.S. Nuclear Regulatory Commission*, 680 F.2d 810, 815-17 (D.C. Cir. 1982). There, the Court explained that it had "narrowly construed the term 'final order'" in the relevant judicial review statute as an order that "imposes an obligation, denies a right, or fixes some legal relationship, usually at the consummation of an administrative process." *Id.* at 815. Thus, a final order in an adjudication is normally "one that disposes of all issues as to all parties." *Id.* Applying that rule, the Court

held it lacked jurisdiction to review an agency action within a not-yet-completed adjudication that prohibited a party from engaging in "cross-examination and discovery." *Id.* at 811-12. The Court explained that the agency's order, establishing the scope and limits of the administrative hearing, "mark[ed] the very beginning of the adjudicatory process" and was "generally viewed as interlocutory," and thus did "not constitute final agency action that is subject to judicial review." *Id.* at 816-17.

B. Because Petitioners Can Seek Judicial Review from DEA's Final Rescheduling Decision, Interlocutory Review Is Unwarranted

1. Under 21 U.S.C. § 877, "any person aggrieved by a final decision" by DEA may petition for judicial review. If petitioners are aggrieved by DEA's final rescheduling decision and satisfy Article III standing, they can petition for review in this Court. In that jurisdictionally proper petition, petitioners could challenge not only DEA's final substantive decision but may also assert that DEA erred in reaching that decision because it did not select them as participants in the rulemaking hearing. That "availability of relief on review of a final order * * * dictates against judicial review at this time." *Natural Resources Defense Council*, 680 F.2d at 816; *accord Lynchburg Gas Co. v. Federal Power Commission*, 284 F.2d 756, 759-60 (3d Cir. 1960) (dismissing petition challenging an interim order denying

intervention where the petitioner "can obtain proper relief on review of the final order").

A different result might obtain if petitioners were prohibited from seeking judicial review at the end of the administrative proceeding, and an interlocutory petition was the only possible avenue for judicial review. That was the case in *Public Service Commission of New York v. Federal Power Commission*, 284 F.2d 200 (D.C. Cir. 1960), where the federal agency denied New York's motion to intervene in the administrative proceeding. Unlike § 877, which allows "any person" to seek judicial review, the statute in *Public Service Commission* limited judicial review to "any *party* to a proceeding aggrieved by an order" of the agency. *Id.* at 203 (emphasis added). The Court construed that language to mean that "a would-be intervenor whose application to intervene has been denied is not a party to the full proceeding upon the merits and is not aggrieved, within the statutory meaning," by "the final order by the Commission upon the merits." *Id.* at 204.

Under that construction of the review provision, New York could not receive judicial review at the end of the proceeding. On that basis, the Court held that New York could seek immediate judicial review from the denial of its intervention motion, reasoning that New York was "a party to

the proceeding in a particular and peculiar, limited sense" of its intervention motion, and was aggrieved by it sufficiently to trigger a statutory right to judicial review. *Public Service Commission*, 284 F.2d at 203-04. This Court later described *Public Service Commission* as a situation where "the order denying intervention represents the end of the line," and the failure to achieve party status means "the putative intervenor could not later seek review of the final [decision] on the merits." *Alaska v. FERC*, 980 F.2d 761, 763 (D.C. Cir. 1992).[3]

The same logic applied to this Court's exercise of jurisdiction in *Tourus Records, Inc. v. DEA*, 259 F.3d 731 (D.C. Cir. 2001), which concerned a DEA administrative forfeiture proceeding. The then-applicable statutes and regulations required a claimant to post a $5,000 bond to assert an interest in the seized property. If no bond was posted, "administrative forfeiture occur[red] by default" and judicial review was limited to whether the forfeiture procedures were followed and complied with due process. *Rodriguez v. U.S. Department of Justice*, 4 F. App'x 104,

[3] The same concerns animate the rule for immediate judicial review when a district court denies intervention as of right. *Cf. Brotherhood of Railroad Trainmen v. Baltimore & Ohio Railroad Co.*, 331 U.S. 519, 524 (1947) (district court denial of intervention as of right is immediately appealable because the would-be intervenor "cannot appeal from any subsequent order or judgment in the proceeding unless he does intervene").

106-07 (2d Cir. 2001); *Gonzalez-Gonzalez v. United States*, 257 F.3d 31, 35 (1st Cir. 2001).[4] In *Tourus Records*, DEA denied the claimant's request to waive the bond requirement and proceed in forma pauperis. 259 F.3d at 733. This Court held it had jurisdiction to review that decision under 21 U.S.C. § 877 as a "final determinatio[n]." *Id.* at 734. That jurisdictional holding was appropriate, because without immediate review the claimant could not challenge the bond requirement or the substantive correctness of the forfeiture.

2. That, however, is not the statutory framework applicable to DEA rescheduling decisions. As explained, the statute does not require petitioners to be parties to the administrative proceeding, and petitioners have exhausted their administrative remedies by seeking to participate in the hearing. If they are aggrieved by DEA's final decision on rescheduling and otherwise satisfy Article III standing, they can seek this Court's review.

Moreover, DEA has made clear that it will consider petitioners' written comments made in favor of rescheduling, in addition to the many

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[4] DEA forfeitures use the procedures as forfeitures under the customs laws. 21 U.S.C. § 881(d). Those statutes, in turn, required forfeiture claimants to post a $5,000 bond to obtain district court review—otherwise, the seized goods are summarily declared forfeited. 19 U.S.C. §§ 1608-1609. Congress later "abolished the bond requirement" for forfeitures initiated after 2000. *Tourus Records*, 259 F.3d at 733 n.2.

other written comments DEA received in response to its rulemaking. The public submitted 43,564 comments in response to the proposed rescheduling, *supra* p. 8, and the Attorney General explained that these comments "will be offered as evidence at the hearing" under 21 C.F.R. § 1308.43(g), and will be considered so long as they are "competent, relevant, material, and not unduly repetitive," 89 Fed. Reg. 44597, 44598 (May 21, 2024). Petitioners assert that the agency will not actually consider their comments, Br. 29, but the Attorney General has made clear that the Department will do so. 89 Fed. Reg. at 44598; *see also* 89 Fed. Reg. 70148, 70149 (Aug, 29, 2024) (Administrator's similar explanation).

It is true that some comments may not be "competent, relevant, material," or may be "unduly repetitious." 21 C.F.R. § 1316.59(a).[5] But to

[5] It is unclear, for instance, what level of consideration the Administrator or the Attorney General should give to the comment "I believe that Marijuana should be legalize in all states and made where state have to stop arrest for using processing." Regulations.gov, *Comment of Kenneth Terral*, https://perma.cc/F7ML-RMQ2. By contrast, the Administrator is certainly able to consider the 11-page written comment submitted by the National Organization for the Reform of Marijuana Laws that supported rescheduling and included citations to and summaries of medical studies concerning marijuana use. Regulations.gov, *Comment of National Organization for the Reform of Marijuana Laws*, https://perma.cc/B2N3-5MBE. So too, the Administrator may consider the 18-page comment submitted by the Substance Abuse Program Administrators Association that opposed rescheduling, relying on various medical and safety studies. Regulations.gov, *Comment of Substance Abuse Program Administrators Association*, https://perma.cc/PWQ7-25PF.

the extent that there has been any indication that none of the comments will be admitted as evidence at the hearing, any such error will be corrected by the Administrator. 5 U.S.C. § 557(b) (the agency on review of an ALJ decision "has all the powers which it would have in making the initial decision"); 21 C.F.R. § 1308.45 (requiring the ALJ to "certif[y] the record to the Administrator" for review).

DEA's decision to consider petitioners' written comments—but to not add petitioners to the many other participants who will present live testimony, argument, and cross-examination—"does not constitute such an 'extreme instance' justifying immediate judicial review." *Natural Resources Defense Council*, 680 F.2d at 816. DEA "restrictions" on petitioners' participation in the rulemaking do "not interfere with [petitioners'] 'ability to raise [their] claims'" after a final agency decision, and so "the rationale for allowing immediate interlocutory appeal [does] not apply." *Alaska*, 980 F.2d at 763.

Deferring judicial review until there is a final decision not only comports with the statutory text but also makes practical sense. It is possible that DEA's ultimate scheduling decision will align with petitioners' preferences, granting them "the relief [they] seek[] from the agency, thereby avoiding judicial review entirely." *Natural Resources Defense*

Council, 680 F.2d at 817. And waiting until there the Administrator issued a final decision ensures that "the court may be able to consider all" procedural and substantive "issues in a single review proceeding." *Id.*

Thus, the agency's procedural, interim orders "in the course of a proceeding do not constitute a final order justifying judicial review" when petitioners can seek "relief from the [ultimate] final order." *Thermal Ecology Must Be Preserved v. Atomic Energy Commission*, 433 F.2d 524, 526 (D.C. Cir. 1970) (per curiam). Agencies, of course, must be cognizant that prejudicial errors in its interim orders might result in reversal and "condemn its proceeding" to be redone. *Id.* But that possibility is balanced against the other "advantages of an administrative process," and Congress judged that the process should not "be clogged" by "interlocutory appeals to the courts." *Id.*

3. Petitioners argue for the opposite course. They would have this Court decide interlocutory appeals determining, not just who may present live testimony in the hearing, but whether the agency has reasonably explained its allocation of time to each participant. Br. 37-38. Petitioners argue that "[t]o be regarded as rational," DEA must consider and explain away "feasible alternatives of more participants but less time per participant" than the allocated "90 minutes to present testimony, two

minutes for opening statements, 10 minutes for closing argument, and 20 minutes for cross examination." *Id.* Those decidedly non-final, interim decisions setting forth the procedures for conducting the hearing are not subject to immediate review under 21 U.S.C. § 877.

C. Petitioners Do Not Invoke This Court's Mandamus Authority

Because petitioners do not challenge a DEA "final determinatio[n]," 21 U.S.C. § 877, the only potential basis for jurisdiction would be this Court's mandamus authority to control and adjust pending agency proceedings that will eventually result in an order that can be directly reviewed in this Court. *Telecommunications Research and Action Center v. FCC*, 750 F.2d 70, 75-77 (D.C. Cir. 1984); *accord In re Multidisciplinary Association for Psychedelic Studies*, 2004 WL 2672303, at *1 (D.C. Cir. Nov. 22, 2004) (per curiam) (reviewing pending DEA proceedings under mandamus standards). Petitioners do not invoke this Court's mandamus authority, and they fail to demonstrate the necessary predicates to mandamus: that they have a clear and indisputable right to appear in person at the hearing, and that there is "no other adequate means to attain" relief, such as "the regular appeals process." *Cheney v. U.S. District Court*, 542 U.S. 367, 380-81 (2004). Accordingly, that basis of jurisdiction is not properly before the Court.

II. DEA Reasonably Limited Participation In The Rulemaking Hearing And Will Consider Petitioners' Written Comments

A. As this Court has recognized, "[n]o principle of administrative law is more firmly established than that of agency control of its own calendar." *City of San Antonio v. Civil Aeronautics Board*, 374 F.2d 326, 329 (D.C. Cir. 1967). Here, permitting argument, testimony, and cross-examination from 163 different entities on a variety of different topics "could produce a proceeding of virtually unlimited proportions and would seriously delay" DEA's consideration of whether marijuana should be rescheduled, "a matter which is deemed by the President and the [agency] to be one of high priority." *Id.* The Administrator thus acted reasonably in limiting live participation in the hearing and permitting 25 individuals and entities to present testimony and argument.

This Court reached the same conclusion in holding that the Civil Aeronautics Board (in conducting a proceeding to study air flight) acted appropriately in limiting its consideration to evidence and applications from 25 cities. *City of San Antonio*, 374 F.2d at 327-29. Cities that had not been selected petitioned for this Court's review, arguing—like petitioners here—that the agency had "prejudged" the evidence by failing to select them for participation, that in choosing some participants but not others the agency acted "illegal[ly] *per se* or arbitrarily applied as to them," and that

the agency's decision otherwise did not comply with the APA. *Id.* at 328. This Court rejected those contentions, holding that the agency acted properly in keeping the proceeding "within manageable limits lest the [agency] be paralyzed in performing its function." *Id.* at 329.

City of San Antonio further rejected the petitioners' argument that "all persons interested in a proceeding have a right to participate as full parties." 374 F.2d at 331. To the contrary, the Court recognized that many entities had a similar interest in the pending proceeding, and "similar treatment would be required for hundreds of other cities similarly situated." *Id.* at 332. The Court declined to require the agency to make scores upon scores of entities full parties to the proceeding. Instead, the Court explained that agencies "should be accorded broad discretion in establishing and applying rules for public participation, including how many are reasonably required to give the [agency] the assistance it needs in vindicating the public interest." *Id.* (ellipses omitted). Accordingly, the agency acted within its discretion in declining to grant the petitioners party-status. *Id.* at 333.

Consistent with that holding, the Administrator "exercis[ed] her discretion in determining the number and nature of participants," App. 391, because it would be impractical to include all 163 individuals and entities

who wished to participate in the formal hearing. Petitioners do not debate the reasonableness of that decision, insisting instead that the decision is procedurally deficient because DEA did not fully explicate this reasoning in writing. Br. 37. But the Court will uphold agency decisions "if the agency's path may reasonably be discerned," as it is here based on the sheer number of would-be participants. *Bowman Transportation, Inc. v. Arkansas-Best Freight Systems, Inc.*, 419 U.S. 281, 286 (1974). And if petitioners or any other entities are dissatisfied with marijuana's scheduling after the entire proceeding concludes, they may seek judicial review of the final rule, or they may separately petition DEA to further reschedule marijuana, 21 U.S.C. § 811(a) (permitting citizen petitions for rescheduling), and their arguments can be "heard by the [agency] in a later proceeding," *City of San Antonio*, 374 F.2d at 330.

The Administrator's decision further reasonably recognized that petitioners have not specified any evidence they would present on the threshold issue that determines whether marijuana can be moved from schedule I at all: whether marijuana has a currently accepted medical use. *See* 21 U.S.C. § 812(b). All controlled substances without a currently accepted medical use must be placed in schedule I—all other controlled substances can only be placed in lesser-controlled schedules. *Id.* Instead,

petitioners assert that they would seek to demonstrate that (1) marijuana's potential for creating dependence is less than certain schedule IV drugs, and (2) DEA's definition of drug abuse is "overbroad because it included marijuana use not harmful to self or others." Br. 45-46. Petitioners fail to explain how this evidence is relevant to the threshold issue of "currently accepted medical use." 21 U.S.C. § 812(b). That statutory standard is an inherent part of the rulemaking, 89 Fed. Reg. at 44599-600 (discussing the standard), and not a "'post hoc' rationalizatio[n]" as petitioners claim, Br. 47. Thus, the agency correctly explained that petitioners "did not sufficiently state with particularity the relevant evidence" petitioners would present "on a material issue of fact." App. 10. Given the focus of petitioners' comments, it was appropriate for the agency to consider their information in written form rather than through live testimony.[6]

"Courts have long accorded agencies broad discretion in fashioning rules to govern public participation and have for the most part permitted

[6] To the extent petitioners are arguing that marijuana risk of abuse warrants placement on schedule IV or V, it is not clear that such scheduling would comport with the United States' obligations under the Single Convention, *see supra* pp. 7-8, and petitioners have not offered any argument on that point. *Compare* John J. Cohrrsen & Lawrence H. Hoover, *The International Control of Dangerous Drugs*, 9 J. Int'l L. & Econ. 81, 95-96 (1974) (describing the Single Convention's requirements), *with* 21 U.S.C. §§ 822-832 (requirements by schedule).

denials of requests" to participate when it "would broaden unduly the issues considered, obstruct or overburden the proceedings, or fail to assist the agency's decisionmaking." *Nichols v. Board of Trustees of Asbestos Workers Local 24 Pension Plan*, 835 F.2d 881, 897 (D.C. Cir. 1987) (footnotes omitted). DEA acted well within that discretion by providing that petitioners may submit their views in writing instead. Although petitioners erroneously intimate that this decision reflects hostility by DEA, this Court has explained that similar case-management orders were "necessitated by practical management considerations" and fail to demonstrate that the agency "acted irrationally or arbitrarily." *City of San Antonio*, 374 F.2d at 330.

B. Petitioners further assert that—separate from their own request for participation in the hearing—the Administrator acted unlawfully in selecting some individuals and entities to participate at the hearing but not selecting others. Br. 39-41. Petitioners make no attempt to explain how they suffer a concrete and particularized injury necessary to satisfy Article III because the agency has not selected *other* people to participate in the hearing. *FDA v. Alliance for Hippocratic Medicine*, 602 U.S. 367, 394 (2024) (a plaintiff "may not establish standing simply based on the

'intensity of the litigant's interest'" and "cannot assert standing simply because they object to [agency's] actions").

Petitioners' suggestions that DEA has made up its mind *against* rescheduling are not well-founded. Br. 41. Here, the Department of Justice has proposed to transfer marijuana to schedule III and will present evidence consistent with that proposal. 89 Fed. Reg. at 44601 (discussing the evidence that DEA believes "may be relevant"); App. 405 (explaining that the Administrator is "the proponent of the notice of proposed rulemaking"). The decisionmakers of course will keep an open mind and will issue a final determination based upon reasoned decisionmaking.

C. For similar reasons, petitioners are mistaken in asserting that they are an "interested person" under 21 C.F.R. § 1300.01(b). Br. 43-45. The regulation defines "interested person" to mean "any person adversely affected or aggrieved by any rule or proposed rule." 21 C.F.R. § 1300.01. Petitioners make no effort to explain—either in their request for participation or in their opening brief—how they would be "adversely affected or aggrieved" by the "proposed rule" rescheduling marijuana. They are thus not similarly situated to other individuals who assert that they would be so harmed.

Although petitioners seek to argue that they were treated differently from similarly situated entities who were selected to participate in the rulemaking, Br. 46-47, those entities were not similarly situated to petitioners. The organization Cannabis Industry Victims Educating Litigators submitted a 512-page comment in response to the proposed rulemaking asserting (with various exhibits) that marijuana has not been recognized "as a legitimate medication that is FDA-approved to treat" medical conditions.[7] The International Association of Chiefs of Police asserted that the proposed rule would adversely affect "the ability of police agencies to protect the public" and sought to address diversion potential, asserted complications without "uniform federal standards," and "the complexities of distinguishing between lawful medical use and" recreational use.[8] Physician Kenneth Finn asserted that the lack of "dosing guidelines or care standards" for marijuana would adversely affect his ability to prescribe or administer marijuana to his patients.[9]

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[7] Regulations.gov, *Comment of Cannabis Industry Victims Educating Litigators*, Appendix E at 2, https://perma.cc/M4FD-8WKD.

[8] Regulations.gov, *Comment of International Association of Chiefs of Police* at 1-2, https://perma.cc/CBH4-RXML.

[9] App. 360; *see also* Regulations.gov, *Comment of Kenneth Finn*, Attachment 3 at 3, https://perma.cc/95NB-ESL6.

These participants thus sought to present evidence that either addressed whether marijuana has a currently accepted medical use (required for rescheduling) or that rescheduling may adversely affect them. Petitioners did not seek to present evidence in either category.

D. Petitioners similarly err in asserting that DEA acted inappropriately in asking other would-be participants to clarify their interest and evidence in the proceeding. Br. 50-51. The context of that correspondence demonstrates that DEA was attempting to understand whether the individuals qualified as interested parties under the regulation and whether they would present relevant evidence.

Aubree Adams, for instance, asserted that she would be personally harmed by the rescheduling of marijuana and that it was "imperative" that she participate in the rulemaking. App. 431. DEA responded by asking Adams to "provide additional information establishing that you are a 'person adversely affected or aggrieved by' the proposed rule," to qualify as "an 'interested person'" under 21 C.F.R. § 1300.01(b). App. 1509. DEA also requested, given the basis of the hearing, for Adams to "provide additional information describing the relevant evidence on a material issue of fact you intend to present during the hearing." App. 1509. DEA then reviewed Adams' clarifications, App. 758-70, and determined that she did not qualify

as an "interested person" under the regulations and did not "sufficiently state with particularity the relevant evidence" she intended to present, App. 1524. The fact that DEA asked for clarification when it was unsure of a participant's interest or proposed testimony serves to confirm that the agency acted diligently and carefully in reviewing requests for participation.

III. The DEA Administrator Has Authority To Oversee And Manage The Formal Rulemaking

The Attorney General has generally delegated the execution of the Controlled Substances Act to the DEA Administrator. 28 C.F.R. § 0.100(b). That delegation includes the authority to oversee rescheduling hearings. *See Alliance for Cannabis Therapeutics v. DEA*, 15 F.3d 1131, 1133-34 (D.C. Cir. 1994) (rescheduling hearing for marijuana); 51 Fed. Reg. 36552, 36552-53 (Oct. 14, 1986) (scheduling hearing for 3,4-methylenedioxymethamphetamine). The Administrator may preside at the hearing personally or the matter may be assigned to an ALJ. 5 U.S.C. § 556(b). Like the heads of other agencies, the Administrator must deal with the press of other enforcement and policymaking matters that require attention, and so the oversight of a single but significant rulemaking is usually assigned to an ALJ. Consistent with that usual practice, the Attorney General provided that an ALJ would preside at the hearing here. 89 Fed. Reg. at 44598.

ALJs may generally "regulate the course of the hearing," including by receiving evidence, administering oaths, etc., 5 U.S.C. § 556(c)(1)-(11), but they do so subject to the agency's rules and directives, *id.* § 556(c). Thus, the Administrator may empower ALJs to make certain discretionary rulings, *see, e.g.*, 21 C.F.R. § 1316.55 (prehearing rulings); *id.* § 1316.62 (interlocutory appeals), and may likewise disable ALJs from making other rulings, *see, e.g.*, *id.* § 1316.56 (placing the burden of proof on particular parties); *id.* § 1316.58(a) (prohibiting witnesses from reading summaries of their testimony).

Here, the Attorney General directed that the ALJ will perform certain tasks.[10] But in doing so, the Attorney General did not implicitly strip the Administrator (who oversees the ALJ) from exercising the standing authority, embodied in a regulatory delegation, to make determinations regarding the conduct of the rulemaking proceeding.

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[10] "The ALJ will have all powers necessary to conduct a fair hearing, to take all necessary action to avoid delay, and to maintain order. The ALJ's authorities include the power to hold conferences to simplify or determine the issues in the hearing or to consider other matters that may aid in the expeditious disposition of the hearing; require parties to state their position in writing; sign and issue subpoenas to compel the production of documents and materials to the extent necessary to conduct the hearing; examine witnesses and direct witnesses to testify; receive, rule on, exclude, or limit evidence; rule on procedural items; and take any action permitted by the presiding officer under DEA's hearing procedures and the APA." 89 Fed. Reg. at 44598 (citation omitted).

Accordingly, the Administrator asked for interested persons who wished to participate in the hearing to provide written requests by September 2024. 89 Fed. Reg. at 70149. The Administrator explained that she would assess all requests "and make a determination of participants," *id.*, which she did, App. 7-9. That was a familiar exercise of the authority that all agencies possess to oversee and regulate the course of their own proceedings. *See, e.g.*, *Arch Coal*, 888 F.3d at 497-98 (Department of Labor determining which entities should be required to participate in administrative hearing, not leaving that decision to an ALJ). Nothing in the Attorney General's notice of proposed rulemaking, the Controlled Substances Act, or any relevant regulation prohibited the Administrator from selecting two dozen individuals and entities to participate in a thorough, but manageable, hearing. Petitioners fail to identify any authority that undermines the above understanding.

CONCLUSION

The Court should dismiss the petition for lack of jurisdiction or, alternatively, deny the petition on its merits.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

I hereby certify that this brief complies with the requirements of Federal Rule of Appellate Procedure 32(a)(5) and (6) because it has been prepared in 14-point Georgia, a proportionally spaced font.

I further certify that this brief complies with the type-volume limitation of Federal Rule of Appellate Procedure 32(a)(7)(B) because it contains 8,210 words, excluding the parts of the brief exempted under Federal Rule of Appellate Procedure 32(f) and D.C. Circuit Rule 32(e)(1), according to the count of Microsoft Word.

/s/ Daniel Aguilar
Daniel Aguilar

ADDENDUM

TABLE OF CONTENTS

5 U.S.C. § 556. Hearings; Presiding employees; powers and duties; burden of proof; evidence, record as basis of decision

(a) This section applies, according to the provisions thereof, to hearings required by section 553 or 554 of this title to be conducted in accordance with this section.

(b) There shall preside at the taking of evidence--

(1) the agency;

(2) one or more members of the body which comprises the agency; or

(3) one or more administrative law judges appointed under section 3105 of this title.

This subchapter does not supersede the conduct of specified classes of proceedings, in whole or in part, by or before boards or other employees specially provided for by or designated under statute. The functions of presiding employees and of employees participating in decisions in accordance with section 557 of this title shall be conducted in an impartial manner. A presiding or participating employee may at any time disqualify himself. On the filing in good faith of a timely and sufficient affidavit of personal bias or other disqualification of a presiding or participating employee, the agency shall determine the matter as a part of the record and decision in the case.

(c) Subject to published rules of the agency and within its powers, employees presiding at hearings may--

(1) administer oaths and affirmations;

(2) issue subpenas authorized by law;

(3) rule on offers of proof and receive relevant evidence;

(4) take depositions or have depositions taken when the ends of justice would be served;

(5) regulate the course of the hearing;

(6) hold conferences for the settlement or simplification of the issues by consent of the parties or by the use of alternative means of dispute resolution as provided in subchapter IV of this chapter;

(7) inform the parties as to the availability of one or more alternative means of dispute resolution, and encourage use of such methods;

(8) require the attendance at any conference held pursuant to paragraph (6) of at least one representative of each party who has authority to negotiate concerning resolution of issues in controversy;

(9) dispose of procedural requests or similar matters;

(10) make or recommend decisions in accordance with section 557 of this title; and

(11) take other action authorized by agency rule consistent with this subchapter.

(d) Except as otherwise provided by statute, the proponent of a rule or order has the burden of proof. Any oral or documentary evidence may be received, but the agency as a matter of policy shall provide for the exclusion of irrelevant, immaterial, or unduly repetitious evidence. A sanction may not be imposed or rule or order issued except on consideration of the whole record or those parts thereof cited by a party and supported by and in accordance with the reliable, probative, and substantial evidence. The agency may, to the extent consistent with the interests of justice and the policy of the underlying statutes administered by the agency, consider a violation of section 557(d) of this title sufficient grounds for a decision adverse to a party who has knowingly committed such violation or knowingly caused such violation to occur. A party is entitled to present his case or defense by oral or documentary evidence, to submit rebuttal evidence, and to conduct such cross-examination as may be required for a full and true disclosure of the facts. In rule making or determining claims for money or benefits or applications for initial licenses an agency may, when a party will not be prejudiced thereby, adopt procedures for the submission of all or part of the evidence in written form.

(e) The transcript of testimony and exhibits, together with all papers and requests filed in the proceeding, constitutes the exclusive record for decision in accordance with section 557 of this title and, on payment of lawfully prescribed costs, shall be made available to the parties. When an

agency decision rests on official notice of a material fact not appearing in the evidence in the record, a party is entitled, on timely request, to an opportunity to show the contrary.

5 U.S.C. § 557. Initial decisions; conclusiveness; review by agency; submission by parties; contents of decisions; record

(a) This section applies, according to the provisions thereof, when a hearing is required to be conducted in accordance with section 556 of this title.

(b) When the agency did not preside at the reception of the evidence, the presiding employee or, in cases not subject to section 554(d) of this title, an employee qualified to preside at hearings pursuant to section 556 of this title, shall initially decide the case unless the agency requires, either in specific cases or by general rule, the entire record to be certified to it for decision. When the presiding employee makes an initial decision, that decision then becomes the decision of the agency without further proceedings unless there is an appeal to, or review on motion of, the agency within time provided by rule. On appeal from or review of the initial decision, the agency has all the powers which it would have in making the initial decision except as it may limit the issues on notice or by rule. When the agency makes the decision without having presided at the reception of the evidence, the presiding employee or an employee qualified to preside at hearings pursuant to section 556 of this title shall first recommend a decision, except that in rule making or determining applications for initial licenses--

(1) instead thereof the agency may issue a tentative decision or one of its responsible employees may recommend a decision; or

(2) this procedure may be omitted in a case in which the agency finds on the record that due and timely execution of its functions imperatively and unavoidably so requires.

(c) Before a recommended, initial, or tentative decision, or a decision on agency review of the decision of subordinate employees, the parties are entitled to a reasonable opportunity to submit for the consideration of the employees participating in the decisions--

(1) proposed findings and conclusions; or

(2) exceptions to the decisions or recommended decisions of subordinate employees or to tentative agency decisions; and

(3) supporting reasons for the exceptions or proposed findings or conclusions.

The record shall show the ruling on each finding, conclusion, or exception presented. All decisions, including initial, recommended, and tentative decisions, are a part of the record and shall include a statement of--

(A) findings and conclusions, and the reasons or basis therefor, on all the material issues of fact, law, or discretion presented on the record; and

(B) the appropriate rule, order, sanction, relief, or denial thereof.

(d)(1) In any agency proceeding which is subject to subsection (a) of this section, except to the extent required for the disposition of ex parte matters as authorized by law--

(A) no interested person outside the agency shall make or knowingly cause to be made to any member of the body comprising the agency, administrative law judge, or other employee who is or may reasonably be expected to be involved in the decisional process of the proceeding, an ex parte communication relevant to the merits of the proceeding;

(B) no member of the body comprising the agency, administrative law judge, or other employee who is or may reasonably be expected to be involved in the decisional process of the proceeding, shall make or knowingly cause to be made to any interested person outside the agency an ex parte communication relevant to the merits of the proceeding;

(C) a member of the body comprising the agency, administrative law judge, or other employee who is or may reasonably be expected to be involved in the decisional process of such proceeding who receives, or who makes or knowingly causes to be made, a communication prohibited by this subsection shall place on the public record of the proceeding:

(i) all such written communications;

(ii) memoranda stating the substance of all such oral communications; and

(iii) all written responses, and memoranda stating the substance of all oral responses, to the materials described in clauses (i) and (ii) of this subparagraph;

(D) upon receipt of a communication knowingly made or knowingly caused to be made by a party in violation of this subsection, the agency, administrative law judge, or other employee presiding at the hearing may, to the extent consistent with the interests of justice and the policy of the underlying statutes, require the party to show cause why his claim or interest in the proceeding should not be dismissed, denied, disregarded, or otherwise adversely affected on account of such violation; and

(E) the prohibitions of this subsection shall apply beginning at such time as the agency may designate, but in no case shall they begin to apply later than the time at which a proceeding is noticed for hearing unless the person responsible for the communication has knowledge that it will be noticed, in which case the prohibitions shall apply beginning at the time of his acquisition of such knowledge.

(2) This subsection does not constitute authority to withhold information from Congress.

21 U.S.C. § 811. Authority and criteria for classification of substances

(a) Rules and regulations of Attorney General; hearing

The Attorney General shall apply the provisions of this subchapter to the controlled substances listed in the schedules established by section 812 of this title and to any other drug or other substance added to such schedules under this subchapter. Except as provided in subsections (d) and (e), the Attorney General may by rule--

(1) add to such a schedule or transfer between such schedules any drug or other substance if he--

(A) finds that such drug or other substance has a potential for abuse, and

(B) makes with respect to such drug or other substance the findings prescribed by subsection (b) of section 812 of this title for the schedule in which such drug is to be placed; or

(2) remove any drug or other substance from the schedules if he finds that the drug or other substance does not meet the requirements for inclusion in any schedule.

Rules of the Attorney General under this subsection shall be made on the record after opportunity for a hearing pursuant to the rulemaking procedures prescribed by subchapter II of chapter 5 of Title 5. Proceedings for the issuance, amendment, or repeal of such rules may be initiated by the Attorney General (1) on his own motion, (2) at the request of the Secretary, or (3) on the petition of any interested party.

(b) Evaluation of drugs and other substances

The Attorney General shall, before initiating proceedings under subsection (a) to control a drug or other substance or to remove a drug or other substance entirely from the schedules, and after gathering the necessary data, request from the Secretary a scientific and medical evaluation, and his recommendations, as to whether such drug or other substance should be so controlled or removed as a controlled substance. In making such evaluation and recommendations, the Secretary shall consider the factors listed in paragraphs (2), (3), (6), (7), and (8) of subsection (c) and any scientific or medical considerations involved in paragraphs (1), (4), and (5) of such subsection. The recommendations of the Secretary shall include recommendations with respect to the appropriate schedule, if any, under which such drug or other substance should be listed. The evaluation and the recommendations of the Secretary shall be made in writing and submitted to the Attorney General within a reasonable time. The recommendations of the Secretary to the Attorney General shall be binding on the Attorney General as to such scientific and medical matters, and if the Secretary recommends that a drug or other substance not be controlled, the Attorney General shall not control the drug or other substance. If the Attorney General determines that these facts and all other relevant data constitute substantial evidence of potential for abuse such as to warrant control or substantial evidence that the drug or other substance should be

removed entirely from the schedules, he shall initiate proceedings for control or removal, as the case may be, under subsection (a).

(c) Factors determinative of control or removal from schedules

In making any finding under subsection (a) of this section or under subsection (b) of section 812 of this title, the Attorney General shall consider the following factors with respect to each drug or other substance proposed to be controlled or removed from the schedules:

(1) Its actual or relative potential for abuse.

(2) Scientific evidence of its pharmacological effect, if known.

(3) The state of current scientific knowledge regarding the drug or other substance.

(4) Its history and current pattern of abuse.

(5) The scope, duration, and significance of abuse.

(6) What, if any, risk there is to the public health.

(7) Its psychic or physiological dependence liability.

(8) Whether the substance is an immediate precursor of a substance already controlled under this subchapter.

* * *

21 U.S.C. § 812. Schedules of Controlled Substances

(a) Establishment

There are established five schedules of controlled substances, to be known as schedules I, II, III, IV, and V. Such schedules shall initially consist of the substances listed in this section. The schedules established by this section shall be updated and republished on a semiannual basis during the two-year period beginning one year after October 27, 1970, and shall be updated and republished on an annual basis thereafter.

(b) Placement on schedules; findings required

Except where control is required by United States obligations under an international treaty, convention, or protocol, in effect on October 27, 1970, and except in the case of an immediate precursor, a drug or other substance may not be placed in any schedule unless the findings required for such schedule are made with respect to such drug or other substance. The findings required for each of the schedules are as follows:

(1) Schedule I--

(A) The drug or other substance has a high potential for abuse.

(B) The drug or other substance has no currently accepted medical use in treatment in the United States.

(C) There is a lack of accepted safety for use of the drug or other substance under medical supervision.

(2) Schedule II--

(A) The drug or other substance has a high potential for abuse.

(B) The drug or other substance has a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions.

(C) Abuse of the drug or other substances may lead to severe psychological or physical dependence.

(3) Schedule III--

(A) The drug or other substance has a potential for abuse less than the drugs or other substances in schedules I and II.

(B) The drug or other substance has a currently accepted medical use in treatment in the United States.

(C) Abuse of the drug or other substance may lead to moderate or low physical dependence or high psychological dependence.

(4) Schedule IV--

(A) The drug or other substance has a low potential for abuse relative to the drugs or other substances in schedule III.

(B) The drug or other substance has a currently accepted medical use in treatment in the United States.

(C) Abuse of the drug or other substance may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in schedule III.

(5) Schedule V--

(A) The drug or other substance has a low potential for abuse relative to the drugs or other substances in schedule IV.

(B) The drug or other substance has a currently accepted medical use in treatment in the United States.

(C) Abuse of the drug or other substance may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in schedule IV.

21 U.S.C. § 877. Judicial Review

All final determinations, findings, and conclusions of the Attorney General under this subchapter shall be final and conclusive decisions of the matters involved, except that any person aggrieved by a final decision of the Attorney General may obtain review of the decision in the United States Court of Appeals for the District of Columbia or for the circuit in which his principal place of business is located upon petition filed with the court and delivered to the Attorney General within thirty days after notice of the decision. Findings of fact by the Attorney General, if supported by substantial evidence, shall be conclusive.

21 C.F.R. § 1308.43. Initiation of proceedings for rulemaking.

(a) Any interested person may submit a petition to initiate proceedings for the issuance, amendment, or repeal of any rule or regulation issuable pursuant to the provisions of section 201 of the Act.

(b) Petitions shall be submitted in quintuplicate to the Administrator. See the Table of DEA Mailing Addresses in § 1321.01 of this chapter for the current mailing address. Petitions shall be in the following form:

_____ (Date)

Administrator, Drug Enforcement Administration _____ (Mailing Address)

Dear Sir: The undersigned _____ hereby petitions the Administrator to initiate proceedings for the issuance (amendment or repeal) of a rule or regulation pursuant to section 201 of the Controlled Substances Act.

Attached hereto and constituting a part of this petition are the following:

(A) The proposed rule in the form proposed by the petitioner. (If the petitioner seeks the amendment or repeal of an existing rule, the existing rule, together with a reference to the section in the Code of Federal Regulations where it appears, should be included.)

(B) A statement of the grounds which the petitioner relies for the issuance (amendment or repeal) of the rule. (Such grounds shall include a reasonably concise statement of the facts relied upon by the petitioner, including a summary of any relevant medical or scientific evidence known to the petitioner.)

All notices to be sent regarding this petition should be addressed to:

_____ (Name)

_____ (Street Address)

_____ (City and State)

Respectfully yours,

_____ (Signature of petitioner)

(c) Within a reasonable period of time after the receipt of a petition, the Administrator shall notify the petitioner of his acceptance or nonacceptance of the petition, and if not accepted, the reason therefor. The Administrator

need not accept a petition for filing if any of the requirements prescribed in paragraph (b) of this section is lacking or is not set forth so as to be readily understood. If the petitioner desires, he may amend the petition to meet the requirements of paragraph (b) of this section. If accepted for filing, a petition may be denied by the Administrator within a reasonable period of time thereafter if he finds the grounds upon which the petitioner relies are not sufficient to justify the initiation of proceedings.

(d) The Administrator shall, before initiating proceedings for the issuance, amendment, or repeal of any rule either to control a drug or other substance, or to transfer a drug or other substance from one schedule to another, or to remove a drug or other substance entirely from the schedules, and after gathering the necessary data, request from the Secretary a scientific and medical evaluation and the Secretary's recommendations as to whether such drug or other substance should be so controlled, transferred, or removed as a controlled substance. The recommendations of the Secretary to the Administrator shall be binding on the Administrator as to such scientific and medical matters, and if the Secretary recommends that a drug or other substance not be controlled, the Administrator shall not control that drug or other substance.

(e) If the Administrator determines that the scientific and medical evaluation and recommendations of the Secretary and all other relevant data constitute substantial evidence of potential for abuse such as to warrant control or additional control over the drug or other substance, or substantial evidence that the drug or other substances should be subjected to lesser control or removed entirely from the schedules, he shall initiate proceedings for control, transfer, or removal as the case may be.

(f) If and when the Administrator determines to initiate proceedings, he shall publish in the Federal Register general notice of any proposed rule making to issue, amend, or repeal any rule pursuant to section 201 of the Act. Such published notice shall include a statement of the time, place, and nature of any hearings on the proposal in the event a hearing is requested pursuant to § 1308.44. Such hearings may not be commenced until after the expiration of at least 30 days from the date the general notice is published in the Federal Register. Such published notice shall also include a reference to the legal authority under which the rule is proposed, a statement of the proposed rule, and, in the discretion of the Administrator, a summary of the subjects and issues involved.

(g) The Administrator may permit any interested persons to file written comments on or objections to the proposal and shall designate in the notice of proposed rule making the time during which such filings may be made.